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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
96-03	

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on April 18, 2008

Signature /michaelcurtis/

Typed or printed name Michael J. Curtis

Application Number	Filed
10/680,950	October 8, 2003

First Named Inventor	
Robert W. LANGLEY	

Art Unit	Examiner
3761	Leslie R. DEAK

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 54053.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/michaelcurtis/
Signature

Michael J. Curtis
Typed or printed name

303-499-8080
Telephone number

April 18, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/680,950	Confirmation No. 6033
Applicant	:	Robert Langley	
Filed	:	October 8, 2003	
TC/A.U.	:	3761	
Examiner	:	DEAK, Leslie R	
For	:	METHODS AND DEVICES FOR PROCESSING BLOOD	
Docket No.	:	96-03	
Customer No.:		23713	

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April 18, 2008 (Date) /michaelcurtis/ Michael Curtis

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Applicant requests a pre-appeal brief review of the Final Office Action dated January 18, 2008. Applicant has met each of the requirements to file such a request and therefore respectfully requests review of the Examiner's rejections in the Final Office Action for the reasons set forth below. The arguments raised below are not a comprehensive set of Applicant's objections and/or response to the Final Office Action, and Applicant reserves the right to raise additional arguments in response thereto and/or on appeal, including arguments that could have been raised here. This Request is being filed concurrently with a Notice of Appeal.

I. The Examiner's Rejection of the Claims under 35 U.S.C. § 103 over Holmes in View of Elgas is Erroneous

Claims 1-12, 14-15, 17-40, 42-45, 47-50 and 67 are rejected under 35 U.S.C. § 103(a) as being obvious over Holmes (U.S. Pat. No. 6,179,801) in view of Elgas (U.S. Pat. No. 5,980,465). In particular are independent claims 25-27 which recite adjusting the blood removal rate and/or the blood return rate based on the total blood volume of the patient.

To establish a prima facie case of obviousness, there must be some suggestion or motivation to combine or adapt the references; a reasonable expectation of success; and the final combination must teach or suggest all of the claim limitations. See MPEP 2142. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicant respectfully submits that a proper prima facie case of obvious has not been made because the references cited by the Examiner, alone or in combination, do not teach or suggest either adjusting the blood removal flow rate or adjusting the blood return flow rate based on the total blood volume, and therefore do not teach or suggest all of the claim limitations.

Holmes is cited for disclosing a blood processing apparatus and method that determines various parameters of the processing procedure and the total blood volume of the patient. Specifically, Holmes discloses a blood apheresis system where blood is removed from a patient, processed, and a portion of the blood returned to the patient. However, as acknowledged by the Examiner, Holmes fails to disclose the step of adjusting the blood removal rate and/or blood return rate based on the total blood volume (Office Action of January 18, 2008, page 3). The Examiner tries to rectify the deficiencies of Holmes by citing Elgas. However, Elgas does not disclose adjusting the blood removal rate or the blood return rate, and furthermore does not disclose adjusting the blood removal rate or return rate based on the patient's total blood volume.

Elgas discloses a method of tracking a patient's blood volume during cardiac surgery where a heart-lung machine drains blood from the patient, oxygenates the blood, and pumps the blood back to the patient. The patient's blood volume is monitored through the use of a marker substance injected into the patient's bloodstream. If the total blood volume in the patient's circulatory system is too low, intravenous fluids, blood transfusions or blood vessel constricting medication are administered to the patient (column 1, lines 43-47). Adjusting the removal flow rate of blood from the body or the return flow rate of blood back to the body as required by the present claims is not taught or suggested by Elgas. The methods that are taught by Elgas (administration of intravenous fluids fluids, blood transfusions, or medication) do not involve or affect the blood removal rate or return rate in any way. Accordingly, combining Holmes with Elgas does not result in the limitations of the present claims.

In responding to Applicant's previous arguments regarding Elgas, the Examiner states that "Elgas specifically teaches that the circulatory fluid of the patient (consisting of blood and IV fluids) is removed from the vena cave [sic] via a *variable speed roller pump*, indicating that the Elgas device is capable of varying fluid removal rate from the patient" (Page 12 of the Office Action). This, however, is a factual error. Column 2, lines 40-48, of Elgas states that blood is diverted from the vena cava by a cardiac pump 17 through a cardiotomy filter 19, into a venous reservoir 20. The variable-speed roller pump 22 referenced by the Examiner is not used to withdraw blood from the patient, but is used to move the blood from the reservoir 20 to the oxygenation unit 24 after the blood has already been removed from the patient (column 2, lines 44-47).

Furthermore, in the Response to Arguments section of the Office Action, the Examiner states that Elgas is not actually being relied upon to teach adjustment of the blood removal or return rate (Pages 12 and 13 of the Office Action). Instead, the Examiner states that Elgas is being used merely to illustrate that patient blood volume is one of many patient parameters used to control an extracorporeal procedure (Page 13 of the Office Action). In light of the Examiner's acknowledgement that Holmes does not teach adjusting the blood removal or return rate according to the total blood volume, Applicant believes these statements that Elgas does not teach adjusting the blood removal or return rate at all underscore that each and every claim limitation has not been disclosed and that a proper prima facie case for obviousness has not been met in this case.

According to the Examiner's argument, Elgas discloses that maintaining a patient's total blood volume during an extracorporeal procedure is clinically significant and increasing fluid flow to the patient is a good way to maintain total blood volume (Page 3 of the Office Action). However, the "fluid flow" taught by Elgas is not the same as the methods taught in Holmes or the present claims. Elgas does not teach adjusting the blood removal or return rate as required by the present claims. The fluids administered to the patient as taught by Elgas (the administration of intravenous fluids, blood transfusions or medication) in fact teach away from the present claims because they are not removed from the patient to begin with and are independently administered to the patient separately from the blood being returned to the patient. Accordingly, the combination of the methods disclosed by Elgas

with Holmes does not result in adjusting the blood removal or return rate based on the total blood volume. Since the cited references do not teach or suggest each and every limitation required by the present claims, the obvious rejection under 35 USC 103 is improper.

II. The Examiner's Rejection of the Claims as Optimization of a Result-Effective Variable Found in the Prior Art is Also Erroneous

Claims 3-10, 28-31 and 34-39 depend from claims 25-27 discussed above and further recite that the blood removal flow rate and return flow rate are adjusted according to specific characteristics (i.e., in a substantially linear or exponential manner) or according to specific equations. Pursuant to MPEP 2144.05, the Examiner rejects these claims as optimization of a result-effective variable which involves only routine skill in the art. MPEP 2144.05 requires that:

> "A particular parameter must first be recognized as a result effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of such variable might be characterized as routine experimentation. In re Antoine, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)"

The prior art, including Holmes and Elgas as discussed above, has not recognized that blood return flow rate and removal flow rate can be beneficially varied according to total blood volume of the patient. Thus, total blood volume has not been recognized as a result effective variable which achieves a recognized result, such as the adjusted blood removal flow rate and blood return flow rate required by the present claims. Accordingly the requirements of MPEP2144.05 have not been met.

In response to Applicant's previous arguments that total blood volume has not been recognized as a result-effective variable which achieves a recognized result, the Examiner stated that Elgas discloses adjustment of total patient fluid volume via IV infusion as well as a variable speed pump that removes fluid from the patient (Page 13 of the Office Action). The Examiner therefore concludes that fluid removal rate may be used to control patient fluid volume and that taken together the references suggest that manipulation of fluid

removal or return rates are variables able to control patient fluid volume when manipulated (Page 13 of the Office Action). As discussed above, this is based on a factual error. The variable speed pump in Elgas is used to transport blood from a reservoir to an oxygenation unit after the blood has already been removed from the patient by a separate cardiac pump (column 2, lines 40-48). The variable speed pump is not used in Elgas to remove blood from the patient. There is no teaching in Elgas (or Holmes) that the blood removal rate or return rate can be adjusted in order to manipulate or correct total blood volume. Absent some correlation in the prior art between total blood volume and the desired adjustment of the blood removal flow rate or return rate of the present invention, it cannot be said that these claims represent a routine optimization of a result-effective variable.

III. Conclusion.

Because the Examiner's rejection of the pending claims includes legal and factual deficiencies, Applicants are entitled to a pre-appeal brief review of the Final Office Action. Based on the foregoing arguments, Applicants request that the rejection of these claims be withdrawn and the claims allowed.

Respectfully submitted,
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